In the Matter of	)	
	)	
Promoting Expanded Opportunities for Radio	)	
Experimentation and Market Trials under Part 5 of	)	ET Docket No. 10-236
the Commission's Rules and Streamlining Other	)	
Related Rules	)	
	)	
2006 Biennial Review of Telecommunications	)	
Regulations – Part 2 Administered by the	)	ET Docket No. 06-105
Office of Engineering and Technology (OET)	)	

Mayo Clinic Response to Notice of Proposed Rulemaking with Regard to Radio Experimentation and Market Trials Under Part 5 of the Commission's Rules and Streamlining Other Related Rules

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1.0 Introduction

Mayo Clinic supports the proposed rules outlined in the *Federal Register* on February 8, 2011 and offers the following comments for consideration. These comments are based in Mayo's primary value, "The needs of the patient come first", a perspective that guides all our activities and collaborations. Mayo's comments at this time are primarily focused on service concepts through use of the radio spectrum and the various elements throughout the process that enable such service. It should also be noted that some of the points expressed here are similar or complimentary to those voiced by Mayo in 2010 during discussion of "Converged Communications and Health Care Devices Impact on Regulation" (FCC Docket No. ET 10-120/FDA Docket No. FDA-2010-N-0291).

For the past five years the staff of the Mayo Clinic has been planning for the evolving health care delivery environment that will be needed to support the U.S. population in the future. This work is intended to extend the traditional model of care from the current range of primary care (the general practitioner's office), secondary care (small hospitals), and tertiary care (facilities such as Mayo Clinic), to include various types of medical monitoring of individuals not only in the

hospital environment, but wherever they may be, in their homes, offices, or in the continuing care retirement-facilities (CCRC's) that are emerging around the country. As this next generation of health care evolves to include new medical devices and services, wireless technologies will play a critical role. Such new health care service concepts would greatly benefit from the expansion of the Experimental Radio Service (ERS) as suggested in the Notice of Proposed Rulemaking (NPRM).

Mayo clinical and engineering professional staffs are studying the most efficacious ways of deploying and employing a range of advanced electronics and communications technologies in the service of emerging care models. Mayo Clinic has conducted and continues to carry out preclinical trials of tabletop-sized electronic equipment for placement in the patient's home, using communications approaches relying on wired and wireless connectivity, as well as custom-designed and fabricated miniature electronic systems. We are examining the potential value of microminiaturization of electronic systems when and where appropriate. We are extending our present concepts of triage and dispatch centers staffed by clinical specialists and supported by server farms running sophisticated analysis algorithms to monitor these patients in "real time" and to intervene in the patient's care as needed.

We are reexamining our long-standing concepts of chronic care versus acute care in non-hospital settings, and are reviewing the efficacy of body-level, short- and long-haul wireless networks, as well as wired network patient access. Mayo is able to conduct such evaluations and reviews because we have an unique combination of in-house skills: a huge clinical caseload; strong basic *and* translational *and* clinical research; world-class electronics capabilities; a history of collaboration among researchers and clinicians; a long-view patient-centered perspective; the ability to conduct rigorous clinical trials to demonstrate medical efficacy and economic sustainability of any devices or systems targeted for the medical environment; and the ability to modify electronically-based devices or systems in a rapid prototyping, quick-turnaround environment.

2.0 Overarching Themes

Several key themes emerged from Mayo Clinic's review of the proposed rules:

- The language of the proposed rules is commercially oriented and assumes commercial interests and motivations. Additional terminology and considerations are needed to match more accurately the language typically employed within the medical community.

- The types of research that Mayo Clinic and others contemplate requires an expansion of the use cases described in the rules to include not only diagnostic and therapeutic use, but also monitoring and emergency alert message transmission.

- From Mayo Clinic's perspective, residential exclusions within the rules do not match the stated intent to test new devices in real world environments. To be of most benefit the test environments and expected use cases described in the rules need to encompass patients' real world settings which would be outside the manufacturer's or developer's facility. Unless these exclusions are revised, institutions such as Mayo, that are a combined developer, manufacturer and test-bed, will be required to also obtain a zone

license in addition to a medical license. Alternatively, the medical license would require a component of the zone license to allow such testing and new service development activities.

- Mayo encourages the FCC to define clinical trials in these instances in concert with the FDA.

3.0 Specific Comments on Proposed Rules

Of the three new experimental program licenses proposed in the NPRM, the medical license clearly supports technology development activities at the individual patient-worn medical device level. As the rules are currently written, in order to realize a complete system level implementation as a new medical service, the addition of the innovation zone license would be required. Alternatively, the addition of some component of the innovation zone license to the medical license would allow the same opportunity for complete device implementation.

The comments that follow enumerate Mayo Clinic's key points regarding each of the proposed licenses, with specific focus on areas which either support or conflict with the development of new medical devices, systems, and services.

3.1 Research Program Experimental Radio License

While the Research Program Experimental License is targeted towards enhancing the ability of universities, laboratories, and other qualified research institutions to conduct experiments outside the scope of the medical program experimental license, several components of this license also apply to the service level concept associated with new medical devices and systems.

3.1.1 Terminology

Several sections in the NPRM, as well as throughout multiple parts of the regulations, focus on market studies. In the commercial sector, market studies are largely used for acceptance testing of new designs within the target user community. For a medical device application, prior to a market trial in the traditional sense, preclinical and clinical trials are required to verify medical efficacy and patient acceptance. Although patient acceptance in terms of ease of use for a new medical device may in part parallel a market study, other components of acceptance, such as patient compliance, are more closely aligned to the goals and objectives of a clinical trial. As such, additional levels of study need to be included to successfully field a medical grade device.

3.1.2 Technical Capabilities and Staff

The NPRM indicates that the research program experimental license will be limited to organizations which are expected to have the appropriate technical personnel, such as Accreditation Board for Engineering and Technology (ABET) universities, and "nationally recognized non-profit research laboratories." The definition of an ABET-accredited university is clear. However, nationally recognized non-profit research laboratories may need further clarification. Does this language limit eligibility to organizations such as federally funded research and development centers (FFRDC) or does it include other non-profit institutions which also have engineering staff who were trained in ABET-accredited university programs, such as members of our staff at Mayo Clinic?

3.1.3 Testing and the Test Environment

Operations under the research program experimental license are proposed to be restricted to the license holder's campus, which would allow for initial testing in a controlled environment. If the intended end-use for a device is a remote medical monitoring application, real world testing would require relaxing this restriction to include individual homes and CCRC facilities for preclinical tests and clinical studies. This point is further discussed in the medical license section below.

3.1.4 Power Level Limits

Devices and applications designed to operate within the confines of an indoor environment will be attenuated by the building structure to some degree, which could allow power level limits to be relaxed compared to limits imposed on outdoor applications. Power levels suggested in the NPRM, in particular power levels limited by Part 15 rules, are typically adequate to cover a modest size house for non-blocked applications such as 802.11 home networking. However these power levels may be insufficient for patient monitoring applications, particularly if a patient-worn device becomes blocked by the body of a fallen person. For such applications we suggest that power limits imposed by Part 15 rules serve as a guideline, and that adjustments be allowed based on results of real world propagation analysis and the potential to cause interference (or lack thereof) to incumbent users identified in the spectrum dashboard data base. With these factors taken into consideration, power levels necessary to close the communications link during an emergency event could be allowed. In other words, some increase in power is allowed over Part 15 limits such that expected attenuation levels are compensated for. One way to implement such a system without increasing interference potential would be to require such a system to perform dynamic power control to close the link in an emergency situation. In this case power may be increased, within accepted safety limits, only for the duration of the emergency. In a non-emergency situation power limits would be limited by existing Part 15 rules.

3.1.5 Test Parameters

For the research program license, the proposed seven day notice requirement before experiments are conducted seems reasonable; however, what constitutes an experiment may need further definition. Is an experiment a single transmission event or an extended test such as might be needed to support a clinical trial?

Web based registration of experiments in a database which could be made accessible to others operating in the same geographic area also seems reasonable, but specifying the location of the test may require clarification. For example, reporting the exact street address of a test site may violate patient confidentiality. A more general location within an innovation zone, as defined below, may serve as an acceptable alternative. The fact that the innovation zone experiment details are available in an open database should be sufficient to enable contact with the appropriate responsible party in the event an interference issue needs to be resolved. Alternatively, a periodic station ID would also provide a way to discover, through the FCC's license database, the appropriate contact without disclosure of an exact street address (although this comes at a cost for a battery-limited on-body monitoring device).

3.1.6 Public Safety Frequencies

We agree that experiments for non-medical applications should avoid the use of public safety frequencies. However, for the medical monitoring situation in which an emergency event transmission is required, the public safety frequency space may be the most appropriate. This comment assumes that such medical monitoring experiments would be conducted within the spirit of public safety frequency use, in accordance with the rules for eligibility to use public safety frequencies (which state that the user must be a municipality, etc. or non-profit entity whose primary mission is caring for the sick and injured). It also would be expected that use of such frequencies would be coordinated with local emergency communications officials.

3.1.7 Additional Topics

The **five year license term** with renewals as suggested in the NPRM is appropriate because extended clinical trials will be needed as new devices and technologies are incorporated into next-next generation medical devices.

With regard to the limitation that holders of a research license cannot **deploy permanent facilities,** it should be noted that for the purposes of extended studies to support clinical trials, antenna structures must be designed to acceptable safety standards including appropriate wind loading for the region in which the test is conducted. Experiments also will be needed through seasonal changes to validate seasonal variables in propagation simulations such as foliage. In this context such an installation may be difficult to distinguish from a "permanent" installation.

In situations in which a license holder such as Mayo Clinic conducts **experiments over multiple campuses** in varying geographic regions, we would expect that one research license would apply to a given institution as opposed to a specific location. The expectation would be that while engineering services may be spread across the institutional locations, coordination with the central engineering group should be sufficient as long as local points of contact are also included to address local interference issues.

3.2 Medical Program Experimental Radio License

With regard to this license type there are several overarching points to consider:

- In some cases the test-bed facility, manufacturer, and developer may all reside within the health care institution, such as at Mayo Clinic.
- Mayo Clinic supports rigorous demonstration of qualifications and expertise in radio management as a critical component for patient safety.
- Wireless medical device applications involving diagnostic and monitoring devices may also include emergency alert transmissions when these devices detect physiological parameters outside some predefined norm.
- This license also needs to include elements of the zone license if new services are to be supported and developed.

Some points already discussed in our comments regarding the Research license are applicable to this section, specifically with regard to four topics:

- **Test Bed location.** The NPRM questions whether the test-bed location for operations conducted under this license should be limited to the medical campus or to a specific

geographic area. As noted in our comments regarding the Research license, diagnostic and monitoring applications will need to include emergency alert message transmissions and expected use locations will largely be in real world locales, such as the patient's private residence or assisted care facility.

- **Station Identification.** As noted in previous comments, station identification requirements must address the necessity to protect patient confidential information.
- **Interference.** Risk assessment from an interference generation potential as well as interference susceptibility also needs to be evaluated and planned for in the real world environment, especially for body-worn and implanted device applications.
- **Reporting periods.** For research contemplated by Mayo Clinic, the test-bed concept needs to be extended to real world non-hospital settings where many of the new devices being developed will be used. Some tests related to these concepts will include a variety of home environments and span time frames of varying lengths. Mayo is supportive of adequate reporting on such testing, but would encourage reporting requirements that do not pose an undue administrative burden, in keeping with the goal of streamlining processes.

3.2.1 Marketing and Equipment Authorization

This section of the proposed rules requires clarification or delineation of the difference between introduction of new devices in the commercial realm and introduction of devices in clinical trial environments. The language needs to be expanded to encompass pre-clinical and clinical trials, and must recognize (similar to FDA processes) that in those environments, commercial marketing and sale of devices is not a factor, since devices would only move to marketing and sale once a trial is successfully concluded. The following discussion points and questions illustrate areas requiring clarification.

- With marketing and operations disallowed under existing rules prior to equipment authorization, the pace of development could be negatively impacted for any new devices.
- The current definition of marketing includes advertising or distribution for the purpose of sale or lease of such equipment. How might this apply to a medical device which is lent to another medical institution for the purpose of efficacy validation by a third party evaluator?
- This type of equipment sharing is quite different than a typical commercial application where competitive issues would prevent this type of test. For a medical application such testing is not only commonplace, but is *expected* before the new medical device is accepted within the medical community.
- Would fielding of new medical devices as part of the clinical trial process be considered limited marketing?
- The NPRM suggests that two types of trials, product development and market trials, are to be included in the revised rules. We suggest that a medical device be differentiated from a more general commercial application, either by including in the product development definition new medical devices used in a clinical trial or alternatively, providing a third category for these types of devices only.
- It will be important for researchers to understand, within the new subpart providing for two types of trials, whether patient compliance is a component of customer acceptability within the definition of a market trial.

3.2.2 Evaluation Kits

An alternative way to categorize devices during clinical trial validation studies would be under the definition of evaluation kits. As these devices may be lent to another health care provider to validate clinical trials, not sold or leased as defined under marketing, ownership would typically be retained by the original equipment developer, which is consistent with current rules. In this application, evaluation kits would be used to validate a device from a clinical perspective, rather than to promote use of a new device in a new third party design such as would typically be the case for a new integrated circuit.

3.2.3 Testing

Testing of new wireless medical devices in a controlled environment is critical for initial validation that the device meets design goals but is not sufficient to field such a device outside the hospital/clinic environment. The focus of many new devices currently being designed and developed is on remote monitoring outside the confines of the medical institution. In this case, it is critical that these devices be evaluated in a preclinical trial setting in a real world environment. Issues such as device tolerance to potential interference sources as well as patient acceptance and ability to use the device without the benefit of close observation/assistance in the clinical environment are not only critical but should be a requirement. Specifically, we suggest that:

- The limitation of the medical experimental license to therapeutic and diagnostic medical equipment should be expanded to include monitoring and emergency alert message transmissions.
- Station identification may not be appropriate from a patient privacy perspective.
- Risk assessment needs to include devices tested in a real-world environment to assure that they not only meet interference standards in the hospital setting but also in the patient's real-world setting.
- Operations conducted under a medical experimental license need to extend beyond the licensee's medical campus if these operations are to include remote monitoring, especially for body-worn and implanted devices.

3.2.4 Technical Requirements

We would expect that in such cases, to be legally operated prior to equipment authorization, certain technical requirements would still need to be met. For example, in a new device design such as a wireless on-body medical device, characteristics such antenna radiation pattern, transmission power, harmonics, spurious emissions, etc. would still need to be characterized. By contrast, applications using a commercial antenna system such as might be the case when deploying an innovation zone communications system to support a new medical service, the manufacturer-supplied antenna parameters and transmitter specifications would be used if unaltered. Again for any custom hardware developed, including the antenna structure, it would be expected that the appropriate characterization of custom elements would be performed to support simulations needed to estimate coverage and any resulting interference potential. As previously noted, a third party industry partner could be utilized if in-house resources are not available.

3.3 Innovation Zone Program Experimental Radio License

As noted in preceding comments, the medical program experimental license addresses a portion of a new wireless medical service but does not cover all the components needed to develop a complete experimental service.

3.3.1 Spectrum Use

Specifically, the communications required between an on-body medical monitoring device and a medical monitoring station will need to include transmissions from the user's expected use location, i.e. the patient's individual real world setting such as a private residence or assisted care facility, to some remote monitoring location such as a local hospital or clinic.

For spectrally remote locations such as Mayo Clinic's headquarters in Rochester Minnesota, a model such as that used for television white spaces appears well suited for identifying an appropriate geographic area. The suggestion that spectrum sensing could be used as one way to manage spectral use is intriguing, especially in the event that a previously undetected interference source compromises a medical device during an emergency event. However, the power required to implement this feature on a battery limited on-body device is of concern. For a multiple transmission scheme, such as a communications path between an on-body device to a wireless gateway device, then another from the gateway device to the medical monitoring location, spectrum sensing for the latter may be a viable option, given that this second link is operated from "wall-plug" power.

3.3.2 Standards and Accreditation Requirements

Mayo recognizes the importance of applying engineering best practices, including minimizing the transmitted power necessary to cover a given geographic area and providing for proper radio management to minimize the chances for interference to incumbent users. Experiments will also need to prove clinical efficacy and verification of system reliability against robust standards similar to that which would be expected for a public safety application. We would expect that for innovation zone applications, engineering tasks for radio management such as propagation simulations would need to be conducted which may require an industry partner in instances where the medical institution does not have these skills internally. For a non-profit entity such as a medical institution, we suggest that documenting that the institution has the appropriate engineering personnel on staff, who received their training in ABET-accredited university engineering training programs, be sufficient to not require a third party industry partner.

3.3.3 Reporting Requirements

We suggest that for a medical application such as the experimental service we describe throughout these comments, reporting requirements would be similar to the medical program license as this is part of an overall system. Reporting requirements including identification of the geographic area, frequencies to be used, transmit power levels, etc. for license application, and seven day lead time required before the start of experimental operations, would also all need to take into consideration preservation of patient confidentiality such as the street address of an individual participating in the study.

3.3.4 Definition of "Experiment"

If the innovation zone license remains a separate license class, then for medical applications in particular, clarification regarding the definition of an experiment is necessary. Is an experiment a single transmission, the duration of a clinical trial, etc.?

3.3.5 Multiple Innovation Zone Licenses

In the event that multiple innovation zone licenses are allowed in a common geographic area, the applications for each license may be very diverse. As an example, a medical service experiment may carry life-critical transmissions, whereas a new commercial application likely would not. In such an instance Mayo suggests that for the medical device application, unused local spectrum identified for such experiments be protected and assigned to a single license holder. This approach would allow testing in an environment similar to a public safety application. However, if spectrum sensing and dynamic frequency assignment is required, then all unused frequency space identified as available within the geographic area should be allowed for all licensees in the defined area. For experiments conducted in the public frequency space we would also expect that coordination with local/regional public safety communications officials would be required.

4.0 Conclusion

Mayo Clinic appreciates the opportunity to offer these comments and suggestions. We would be happy to discuss these points or any other related matters in greater detail.